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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,474	02/27/2002	Irena Bronstein	4085-252-27 CONT	5776

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EXAMINER

RILEY, JEZIA

ART UNIT PAPER NUMBER

1637

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

j/r

Office Action Summary	Application No. 10/083,474	Applicant(s) BRONSTEIN ET AL.	
	Examiner Jezia Riley	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-24 is/are pending in the application.
- 4a) Of the above claim(s) 9,10,12,15-19 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,8,11,13,14,21,23 and 24 is/are rejected.
- 7) ☒ Claim(s) 20 is/are objected to.
- 8) ☒ Claim(s) 7-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of Group II in the reply filed on 1/21/05 is acknowledged. The traversal is on the ground(s) that all the currently pending claims would not impose an undue burden on the examiner. This is not found persuasive because as stated in the restriction requirement filed 10/20/04, the inventions are directed to different composition of matter comprising different structures and functions. These compounds are independent and distinct due to their diverse chemical structures leading thereof to different chemical properties and reactive conditions.

The requirement is still deemed proper and is therefore made FINAL. Additionally applicant elected species depicted on page 12 of the specification for the precursor. After searching said elected, species, the examination of the instant application has been extended to include any chemiluminescent precursor, since said method comprising a species as shown on page 12 of the specification seems free of prior arts.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 7, 8, 11, 13, 14, 21, 23, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dattagupta et al. (U.S. Patent No. 4,794,073) in view of Eggers (Biotechniques Vol.17, No.3, 1994, page 516) in further view of Tsuchiya et al. (US5,672,514).

Regarding claim 7, Dattagupta et al. teach a composition of matter comprising:
a support which comprises an inspectible surface (Dattagupta et al. teach supports for solid-phase hybridization formats, such as polymeric materials in the form of membranes, beads, microtiter plates, etc.; col. 9, lines 65-67., col. 11, lines 60-67., col. 12, lines 1-7 and 60-67., col. 13, lines 1-11), probes are being provided with a chemiluminescent precursor, which precursor can be converted to a chemiluminescent moiety which can be triggered to luminescence (Dattagupta et al. teach nucleic acid probes immobilized on the solid support (col. 12, lines 46-60., col. 13, lines 12-55). The probes comprise a nucleic acid sequence and a chemiluminescent precursor linked to the nucleic acid sequence (col. 2, lines 12-17 and 27-39; col. 8, lines 4-32). The precursor can be converted to a chemiluminescent moiety by a reaction with an oxidant

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and a peroxidase (col. 9, lines 18-40 and 57-65). Regarding claim 8, Dattagupta et al. teach probes which are used for detection of nucleic acids by hybridization, the probes comprising different nucleotides (col. 10, lines 45-67', col. 14, lines 40-56). Any methods can be employed to immobilize probe on surface (col.11-13). Col. 11-12 show that the probe can be labeled through a linker.

However Dattagupta does not show a plurality of oligonucleotides provided on the surface.

Eggers discloses a microchip for quantitative detection of molecules utilizing luminescent groups. Specifically page 517 shows Figure 2 where distinct biological probes are immobilized on a surface and labeled with chemiluminescent tags. The tags can be attached covalently (page 520).

Therefore, it would have been obvious at the time the invention was made to apply the method of Eggers to the chemiluminescent detection method of Dattagupta. The motivation is that DNA target can be quantitatively assessed within seconds due to the high sensitivity (Eggers, abstract). Said DNA –based assays can be used for clinical diagnostic which require the immobilization of hundreds of oligonucleotide on 1-cm² solid support. Such assays are capable of detecting single base changes in a target nucleotide and hence, amenable to genetic disease diagnostics. (Eggers page 522,). Additionally, Tsuchiya et al. discloses that chemiluminescent detecting method comprising biopolymer labeled with a labeling substance and a chemiluminescent substance is well known in the art (col.1-2) and said chemiluminescent substance

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maybe a dioxetane (col. 4 line 66-col.5 line8). The labeling substance produces chemiluminescent by contact between itself and the chemiluminescent substance. And determination of the sequence of the DNA can further be made therefore meaning that the labeling substance viewed as the chemiluminescent moiety of instant claim 14 remains attached to the oligonucleotide (col. 5, lines 8-18). Additionally the chemiluminescent substance contains a sensitizing dye which can change the wavelength of light emitted from the chemiluminescent substance. (col.3, lines 41-44, and col.6).

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7, 8, 11, 13, 21, 23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 5,800,999 in view of Lipschutz et al. (Biotechniques, vol. 19, pp. 442-447, 1995).

This rejection is discussed in the office action mailed 5/6/2004. The rejection is therefore maintained upon filing of a Terminal Disclaimer.

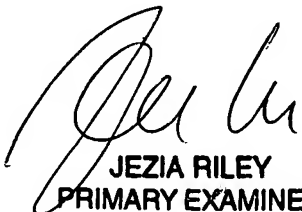
5. Claim 20 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 571-272-0786. The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Thursday, March 17, 2005


JEZIA RILEY
PRIMARY EXAMINER